## APPENDIX C

## ABSTRACT OF PROTOCOL

This protocol is a study of patients with advanced cancer who have failed standard therapy. In an attempt to increase the patient's immune response to the tumor, the interleukin-4 (IL-4) gene will be introduced into a fibroblast line established from the patient. These gene-modified fibroblasts mixed with autologous tumor cells will then be injected into the back of the patient. This injection will augment the immune responses of the patient because a subcutaneous location will be utilized as well as the immune stimulatory effects of the IL-4 secreted by the gene modified fibroblasts. To further evaluate the immune system of the patient to fight their tumor, stimulated lymphocytes will be cultured from the injected tumor itself. These lymphocytes will be expanded in vitro and studied in a number of ways. Animal models have shown that the injection of gene modified tumor cells has important antitumor effects. A second series of injections will be carried out two weeks later. Multiple biopsies of injected sites will be obtained after each immunization.

The patients will be evaluated for antitumor effects engendered by the injection of the gene modified fibroblasts mixed with tumor cells themselves. The injection of gene modified fibroblasts mixed with tumor cells may serve to "immunize" the patient to their tumor and may be amenable to use in a wide variety of tumor types, especially those that are poorly immunogenic. This protocol may also increase the effectiveness of active immunotherapy as well as expand the use of subsequent administration of IL-2 to patients with other malignancies not currently amenable to immunotherapy.